UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF NEW YORK

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KELLI LYNN COATES BACCARO and
BRIAN SCOTT BACCARO,

Plaintiffs,

-v- 1:19-CV-1088

COLOPLAST CORP. and COLOPLAST
MANUFACTURING US, LLC.

Defendants.

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DAVID N. HURD
United States District Judge

MEMORANDUM-DECISION and ORDER

I. INTRODUCTION

On September 4, 2019, wife-and-husband plaintiffs Kelli Lynn Coates Baccaro ("Kelli") and Brian Scott Baccaro ("Brian", collectively the "Baccaros" or "plaintiffs") filed a complaint against defendants Coloplast Corp. and Coloplast Manufacturing US, LLC (collectively "Coloplast" or "defendants"). Roughly speaking, Kelli blames defendants for producing a faulty vaginal mesh called the Altis Single Incision Sling System ("Altis"). Kelli was surgically implanted with an Altis to treat her stress urinary incontinence ("SUI"), which she claims has since caused her any number of debilitating and painful medical complications. For his part, Brian tags along with Kelli's claim, arguing loss of consortium due to Kelli's Altis implant.

In total, the Baccaros allege nine counts in their complaint, all coming under New York common law:[1] (I) negligence; (II) negligent misrepresentation; (III) gross negligence; (IV) design defect; (V) failure to warn; (VI) manufacturing defect; (VII) fraudulent concealment; (VIII) punitive damages; and (IX) loss of consortium.

On December 21, 2020, Coloplast filed a flurry of motions in an attempt to resolve this case in advance of trial. Defendants filed motions to preclude

[1] Because plaintiffs are New York residents and defendants are Delaware corporations with principal places of business in Minnesota, the parties do not dispute that the Court has diversity jurisdiction to hear this case under 28 U.S.C. § 1332. The parties similarly do not dispute that New York law governs plaintiffs' state law claims.

five of the Baccaros' expert witnesses under Federal Rule of Evidence ("Evidence Rule") 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), as well as a motion for summary judgment against the entirety of plaintiffs' complaint under Federal Rule of Civil Procedure ("Rule") 56. Those motions will now be considered on the basis of the submissions and without oral argument.

II. BACKGROUND

On November 16, 2018, Dr. Edward Marici ("Dr. Marici") implanted Kelli with an Altis to treat her SUI.[2] Dkt. 48-2, Defendants' Statement of Material Facts ("DSMF"), ¶ 1. SUI is a not-uncommon condition in women forty-five years old or older that involves urine leaking from the woman's urethra in moments of stress or physical activity. Dkt. 59-3 ("Rosenzweig Report"), pp. 5-6.[3] Altis is a kind of "mesh" woven together from five-millimeter thick strands of a substance called polypropylene. DSMF ¶ 18. Essentially, Altis is intended to support a woman's urethra to help mitigate the effects of SUI. Rosenzweig Report 14-15. The Food and Drug Administration ("FDA") has

[2] The facts are taken from defendants' Statement of Material Facts and other record evidence. Because plaintiffs failed to respond to defendants' Statement of Material Facts as required by Local Rule of the Northern District of New York 56.1(b), the Court will deem those facts to be admitted where properly supported.

[3] Pagination corresponds with CM/ECF. As discussed more fully below, defendants challenge the admissibility of the Rosenzweig Report. The Court only includes a reference to that report here for the purposes of providing a cohesive background and will not rely on the Rosenzweig Report for any other purpose until and unless that report is upheld after defendants' challenge under Evidence Rule 702.

authorized Altis to be marketed for that purpose since November 5, 2012. Dkt. 48-11, pp. 2-3.

Even going into Kelli's implantation surgery, Dr. Marici knew that Altis carried certain risks, and he told Kelli about each one. DSMF ¶ 4. Nevertheless, after weighing Coloplasts' warning materials, his own education and experience, and discussions with other doctors, Dr. Marici thought Altis was the appropriate treatment for Kelli's SUI. *Id.* ¶¶ 4-5, *see id.* ¶ 2 (noting that Dr. Marici selected Altis for plaintiff's surgery). Dr. Marici stands by his decision to implant Kelli with Altis, and he testified that he would still consider using Altis to treat a patient with Kelli's symptoms today. *Id.* ¶ 3.

Safe to say, though, the Baccaros would disagree. On February 5, 2019, roughly three months after her first surgery, Kelli went under Dr. Marici's knife again because her Altis had become exposed after implantation. Dkt. 48-14, p. 2. On February 19, 2019, Dr. Marici conducted a third surgery, apparently to repair the same problem. Dkt. 48-15, p. 2.

On September 20, 2019, a different doctor performed surgery on Kelli again to treat the erosion of her Altis sling. Dkt. 48-16, p. 2. Still, Kelli's problems persisted. Kelli had a fifth and—thus far—final surgery to address erosion of her Altis mesh on June 12, 2020. Dkt. 48-17, p. 2. Kelli's surgeries hoped to treat her ongoing symptoms of pain, bleeding, repeated urinary tract

infections, urinary incontinence, chronic pelvic inflammation, and pain during sexual intercourse. Dkt. 63-2 ("Gold Report"), p. 3.[4]

But even before Kelli's last two surgeries, the Baccaros had already apparently had enough and filed the present complaint on September 4, 2019. Dkt. 1. The parties proceeded through discovery, and each side disclosed the experts they intend to call at trial.

Among the Baccaros' expert disclosures, five in particular need some introduction: (1) William Gold, M.D. ("Dr. Gold") intends to establish specific causation; (2) Bruce Rosenzweig, M.D. ("Dr. Rosenzweig") intends to establish general causation and identify alternate product designs for Altis; (3) Neeraj Kohli, M.D. ("Dr. Kohli") intends to offer similar testimony to Dr. Rosenzweig; (4) Jimmy Mays, Ph.D. ("Dr. Mays") intends to testify concerning the capacity of polypropylene—the fibers Altis is made from—to oxidize and break down once implanted in the body; and (5) Peggy Pence, Ph.D. ("Dr. Pence"), a microbiologist, intends to testify concerning the process of creating a medical device.

On December 21, 2020, Coloplast moved to exclude the opinions and testimony of all five of the Baccaros' expert witnesses. Dkts. 49-53. The

[4] Similarly to the Rosenzweig Report, defendants have challenged the admissibility of the Gold Report as well. That report is also cited here for the sole purpose of providing context for plaintiffs' claims.

same day, defendants filed a motion for summary judgment against plaintiffs' complaint. This decision follows.

III. LEGAL STANDARD

A. Preclusion of Expert Testimony

Evidence Rule 702 permits an expert to give an opinion if each of four conditions are met: (1) the expert possesses specialized knowledge that will be of use to a trier of fact in understanding the evidence or determining a fact; (2) that "testimony is based on sufficient facts or data;" (3) "the testimony is the product of reliable principles and methods;" and (4) the expert has reliably applied those principles and methods to the facts of the case. FED. R. EVID. 702. As a result, a district court must assess whether: (1) the witness is qualified to offer expert testimony; (2) the opinion is based on reliable data and methodology; and (3) the expert's testimony on a particular issue will assist the trier of fact. *Bee v. Novartis Pharm. Corp.*, 18 F. Supp. 3d 268, 300 (E.D.N.Y. 2014) (citing *Nimely v. City of N.Y.*, 414 F.3d 381, 396-97 (2d Cir. 2005)).

In considering reliability, the Supreme Court in *Daubert* endorsed a flexible approach. *In re Mirena IUS Levonorgestrel-Related Prods. Liab. Litig. (No. II)*, 982 F.3d 113, 123 (2d Cir. 2020) (citing *Daubert*, 509 U.S. at 597). The *Daubert* standard does not provide a checklist or a test, but instead looks at experts case-by-case. *In re Mirena*, 982 F.3d at 123.

That case-by-case approach considers: (1) whether the expert's theory or technique is testable; (2) whether that technique has been subjected to peer review and publication; (3) a technique's rate of error and whether standards exist to govern the technique's operation; and (4) whether a particular technique or theory is generally accepted in the scientific community. *In re Mirena*, 982 F.3d at 123.

Daubert and its progeny charge a district court with ensuring that expert evidence does not come in if "there is simply too great an analytical gap between the data and the opinion proffered." *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). In other words, the expert's opinion must be excluded as unreliable if it is "based on data, a methodology, or studies that are simply inadequate to support the conclusions reached[.]" *Nimely*, 414 F.3d at 396.

B. Summary Judgment

Summary judgment under Rule 56 is warranted if the parties' submissions show "that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." *Johnson v. Killian*, 680 F.3d 234, 236 (2d Cir. 2012) (citing FED. R. CIV. P. 56(a)). A fact is "material" if it "might affect the outcome of the suit under the governing law." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). And a dispute of a material fact is "genuine" if "the evidence is such that a reasonable jury could

return a verdict for the nonmoving party." *Id.* The movant bears the burden of pointing the court to the materials that it believes demonstrate the absence of a genuine issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986).

Additionally, a court considering a summary judgment motion "must resolve any ambiguities and draw all inferences from the facts in a light most favorable to the nonmoving party." *Ward v. Stewart*, 286 F. Supp. 3d 321, 327 (N.D.N.Y. 2017) (citing *Jeffreys v. City of New York*, 426 F.3d 549, 553 (2d Cir. 2005)). Even so, a non-movant's conclusory allegations without support from record evidence are insufficient: the non-movant must "put up or shut up." *Weinstock v. Columbia Univ.*, 224 F.3d 33, 41 (2d Cir. 2000). At bottom, summary judgment tasks the Court with assessing the assembled evidence and determining whether a reasonable factfinder could find in the nonmovant's favor. *Treglia v. Town of Manlius*, 313 F.3d 713, 719 (2d Cir. 2002).

IV. DISCUSSION

Many of Coloplast's summary judgment arguments are predicated on one or more of plaintiffs' experts being precluded. Accordingly, the full weight of defendants' summary judgment arguments is wrapped up in which of plaintiffs' experts, if any, are worthy of credit. Therefore, the viability of the Baccaros' experts will be analyzed first.

A. *Daubert* Preclusion

Because Coloplast argues that the entire complaint falls apart if Dr. Gold is precluded, that analysis will begin with him.

1. William Gold, M.D.

Coloplast attacks Dr. Gold's expert report along several fronts. First, defendants argue that Dr. Gold is unqualified to offer opinions in this case because he lacks experience in urogynecology and with synthetic mesh. In fact, Dr. Gold has not even worked with patients since 1996, which is around the time vaginal mesh first hit the market. Dkt. 49-5 ("Gold Dep."), pp. 17-18.

The Baccaros counter that Dr. Gold completed a residency in obstetrics and gynecology at Georgetown University, then spent twenty years teaching in the same field. Gold Report, p. 2. In addition, Dr. Gold testified at his deposition that he has continued to track developments in SUI technologies including mesh even after he stopped actually treating patients. Gold Dep. 17.

Ultimately, Coloplast's arguments may limit the scope of Dr. Gold's qualifications, but does not limit his ability to establish that Altis caused the symptoms afflicting Kelli's health. To do that effectively, he does not need expertise in how to surgically implant a patient with Altis, or even to have ever worked with synthetic mesh.

Drs. Rosenzweig, Kohli, and Mays can testify more generally as to whether Altis can cause negative outcomes once it is implanted in a patient. Dr. Gold need only take the potential outcomes they describe, process those outcomes through his knowledge of vaginal health, and determine whether complications with Altis caused the symptoms allegedly plaguing Kelli. His extensive experience as a professor of obstetrics and gynecology clears that threshold, and he is qualified to offer an expert opinion as to whether Altis caused the symptoms of which Kelli complains.[5] *See, e.g.*, *Lancaster v. Ethicon, Inc.*, 2020 WL 819291, at *8 (N.D.N.Y. Feb. 19, 2020) (finding physician qualified to serve as expert in vaginal mesh case because he completed residency in obstetrics and gynecology and served as assistant professor of gynecology and obstetrics for over fifteen years).

Next, Coloplast targets the reliability of Dr. Gold's findings. Defendants argue that Dr. Gold's report provides scarce support for how he came to the conclusion that Altis caused Kelli's symptoms. They also take issue with Dr. Gold's limited review of Kelli's medical records, his failure to conduct a differential diagnosis, his failure to examine Kelli himself, and his failure to review defendants' expert's deposition.

[5] Defendants also argue that Dr. Gold's mere qualifications as a doctor are not enough to make him qualified to offer an expert opinion. The Court does not rely on Dr. Gold's credentials in such broad strokes. Rather, it is Dr. Gold's expertise in vaginal health that makes him qualified.

Each point Coloplast raises could be used to undercut Dr. Gold's credibility and the weight of his opinion to the jury. And defendants are welcome to bring those points to the jury's attention on cross-examination. Yet none of them makes Dr. Gold's opinion outright unreliable, rather than merely imperfect.

Coloplast's attack on Dr. Gold's opinion for his failure to conduct a differential diagnosis[6] could have rendered his opinion unreliable in other circumstances. Courts in the Second Circuit have allowed a medical expert to testify as to the specific cause of a plaintiff's injury without a differential diagnosis, but only under three sets of circumstances. *See Matthews v. Hewlett-Packard Co.*, 2017 WL 6804075, at *3-4. (S.D.N.Y. Dec. 22, 2017) (collecting cases). First, if the expert is the plaintiff's treating physician. *Id.* at *3. Second, if the connection between the injury and its source is obvious even to a layperson. *Id.* And third, if there are otherwise sufficient indicia of reliability. *Id.* at *4.

Dr. Gold is not Kelli's treating physician, so the first path can be ruled out. The second is a closer call. Kelli's treatment notes from her numerous surgeries contemplate extensive tinkering with the Altis after it was implanted, suggesting strongly that it might have been responsible for her

[6] A differential diagnosis determines the underlying cause of a medical condition by using the process of elimination to pin down the most likely cause of a set of signs and symptoms. *Ruggiero v. Warner-Lambert Co.*, 424 F.3d 249, 254 (2d Cir. 2005) (citation omitted).

symptoms. Dkts. 48-14, p. 2; 48-15, p. 2; 48-16, p. 2; 48-17, p. 2. However, the Court cannot rule out the possibility that some cause unique to Kelli might have led to the problem with the Altis rather than the Altis leading to Kelli's symptoms. The second road to clemency for Dr. Gold's lack of a differential diagnosis is also closed.

But the third is a different story. In fact, some cases employing the "otherwise sufficient indicia of reliability" exception bear a striking resemblance to this one. *See, e.g.*, *Figueroa v. Boston Sci. Corp.*, 254 F. Supp. 2d 361, 367 (S.D.N.Y. 2003). In *Figueroa*, the Southern District found that a medical expert's testimony was reliable in the absence of a differential diagnosis when he reviewed the plaintiff's medical records, reviewed the plaintiff's and his treating physician's depositions, consulted peer-reviewed medical literature, and the timing of the symptoms the plaintiff presented with aligned with the causal event. *Id.*

Dr. Gold did not read Kelli's deposition, or that of her treating physician. However, he did read the reports of five of the Baccaro's other proffered experts, consulted several peer-reviewed medical sources, examined Altis's own product brochures, and consulted a pair of FDA documents concerning Altis. Gold Report 7. In addition, Kelli's symptoms progressed to the point that she needed surgery fewer than three months after she was implanted with Altis. DSMF ¶ 1 (noting that Kelli was implanted with Altis on

November 16, 2018); Dkt. 48-14, p. 2 (describing Kelli's first corrective surgery on February 5, 2019).

Therefore, Dr. Gold's report carries sufficient indicia of reliability notwithstanding the absence of a differential diagnosis, and his methods are reliable. *See, e.g.*, *Figueroa*, 254 F. Supp. 2d at 367 (upholding expert testimony where timing of injuries aligned with incident and expert reviewed medical records, testimony, and peer-reviewed medical literature).

As a consequence, Dr. Gold's expert testimony is largely admissible. Nevertheless, Coloplast still argues that his testimony should be cabined and he should be precluded from testifying about: (1) polypropylene's properties and its capacity to degrade in the human body; (2) the FDA's clearance process; and (3) defendants' corporate culture and their testing methodologies for Altis. The Baccaros seem to concede defendants' first point by only arguing that their other experts and plaintiff herself can testify as to her Altis's degradation. Defendants' motion must be granted on point one. The remaining two points go unaddressed in plaintiffs' responsive brief. Judgment is reserved on defendants' other specific attacks on Dr. Gold's report pending trial.

2. <u>Bruce Rosenzweig, M.D.</u>

Coloplast's next target is Dr. Rosenzweig. Once again, defendants ask for exclusion on both broad and narrow grounds. In terms of their broad attack,

defendants would exclude Dr. Rosenzweig's opinions concerning the viability of safer alternative designs for Altis as unreliable.

Coloplast first complains that Dr. Rosenzweig does not point to any alternative that does not pose the same risks as Altis. However, the Baccaros are not obliged to come up with a pelvic surgery void of any risks, or even void the same types of risks. Plaintiffs only have to prove that their alternatives present lesser risks than Altis does. Dr. Rosenzweig has claimed exactly that and has provided scientific support to back his claims up. Defendants' first argument must be rejected.

Similarly, Coloplast misses the mark by arguing that Dr. Rosenzweig's testimony is unreliable for failing to cite to literature specifically comparing Altis to other options. Dr. Rosenzweig's role is not to parrot scientific literature on the stand. Instead, the Baccaros plan to offer his testimony to explain why certain design features of Altis could cause symptoms in patients. Making the connection between Altis's design features and the potential of those features to cause harm is well within the purview of Dr. Rosenzweig's role as an expert.[7] *See, e.g.*, *Arruda v. C.R. Bard, Inc.*,

[7] As part of their more general arguments against Dr. Rosenzweig's report, defendants also argue more specifically that Dr. Rosenzweig has not presented any alternative procedures to support plaintiffs' design defect claims. Those arguments do not relate to the admissibility of Dr. Rosenzweig's report, but to the merits of plaintiffs' claims. The Court will address these arguments as part of defendants' motion for summary judgment.

2020 WL 4569436, at *9-13 (N.D.N.Y. Aug. 6, 2020) (upholding expert reports of doctors pointing to qualities of vaginal mesh rendering them defective).

With regard to defendants' more specific objections, defendants correctly note that Dr. Rosenzweig has offered precious little support for his claims that Altis's lack of a sheath and use of four-pronged anchors—rather than two pronged—"could" lead to complications.

In support of the former, Dr. Rosenzweig only refers to a note from a 2007 Women's Health Advisory Board Meeting indicating that one of the topics discussed was the "[p]erception that [a] sleeve helps with decreasing infection rate." Rosenzweig Report 49. His support for the dangers of four-pronged anchors is even weaker. Dr. Rosenzweig only mentions that Altis alone uses four-pronged anchors before pivoting to discuss Altis's relatively short length and the reasons that short length poses a danger. If there is any rationale tying the anchors to the short length of the mesh, Dr. Rosenzweig does not point that connection out.

Perhaps Dr. Rosenzweig could have provided support for these contentions by relying on his experience and expertise in vaginal health and surgery. He could also have provided more medical research to support his claim. He did neither. As a result, Coloplast is correct, and Dr. Rosenzweig's opinions concerning a sheath or anchor design must be excluded. *See, e.g.*, *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 611-12 (S.D. W. Va. 2013) (excluding expert

opinion as unreliable when expert only relied on personal experiences and internal documents of defendant company).

Next, Coloplast challenges Dr. Rosenzweig's opinions concerning the size of Altis's pores and its general density. But Dr. Rosenzweig has provided ample support for the notion that Altis possesses relatively small pores and that those pores present heightened risks of bad reactions.[8] Rosenzweig Report 27-28 (citing materials indicating that large pore mesh has pore size of greater than 1500 microns, Altis's pores measure 330 microns,[9] and large pores are less likely to incur negative response after implantation). He provides similar evidence to support that Altis is a relatively heavy mesh. *Id.* (noting that heavier meshes can lead to complications, a "lightweight" mesh has a density of 18-42 grams per square meter, and Altis is 70 grams per square meter). Those opinions, built on multiple medical studies, are reliable and must not be excluded.

The remainder of Coloplast's concerns with Dr. Rosenzweig's expert report deal with the scope of his expertise, rather than the reliability of any of his opinions. Much like with Dr. Gold, those concerns are better left for trial.

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[8] Defendants do not seem to take issue with Dr. Rosenzweig's opinion that Altis is a relatively stiff mesh. Rosenzweig Report 41-49.

[9] Defendants object to plaintiffs' characterization of Altis as a "small-pore" mesh. The Court takes no issue with Altis defining itself as a "macroporous" or "large-pore" mesh in a general sense. Dkt. 53-16, p. 2 (defining "macroporous" as containing pores larger than 75 microns for purposes of hernia mesh). However, for the purposes of this litigation, when the Court says "small pore" it means as a comparative to the 1500 micron metric that plaintiffs' experts claim should be the minimum pore size. Rosenzweig Report 27-28.

3. Neeraj Kohli, M.D.

First, defendants seek to preclude Dr. Kohli from testifying that Altis's complication rates are "unacceptably high" compared to other SUI treatment options.

Coloplast objects that there is no support for Dr. Kohli's position. Indeed, the District Court for the Southern District of Western Virginia came to the same conclusion. *In re Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4582233, at *3 (S.D. W. Va. Sept. 1, 2016) (precluding Dr. Kohli's testimony about unacceptably high complication rate as *ipse dixit*). The Court nevertheless respectfully disagrees.

Dr. Kohli points out precisely the same design features of Altis (small pores, stiff materials, and high density) that featured prominently in Dr. Rosenzweig's report and claims that each of these distinctive design features increases the risk of a bad outcome. Dkt. 61-3 ("Kohli Report"), pp. 6-12. Based on the materials he cites—which defendants do not challenge as unreliable—the Court takes no issue with him taking the further step of supplying his practical opinion that those additional risks make Altis unsafe. In fact, the whole point of an expert witness is to help the trier of fact understand the evidence. FED. R. EVID. 702(a) (requiring expert witness's specialized knowledge to be helpful to trier of fact in understanding evidence or determining fact). Pinning Dr. Kohli's testimony only to the evidence of

the heightened risks presented by Altis's design features without allowing to take the next step of reducing those abstract risks into a brass tacks conclusion would defeat the entire purpose of including Dr. Kohli's testimony at all.

Given Dr. Kohli's abundant support for the proposition that Altis's features increase complication rates, he is well within his rights to testify that, in his experience and based on his unchallenged qualifications as an expert in pelvic reconstructive surgeries, he considers Altis's complication rate to be too high.[10] *See Nimely*, 414 F.3d at 396-97 (stating that opinions must be excluded only if data and studies are inadequate to support conclusions reached).

The rest of Coloplast's objections to Dr. Kohli's report fall squarely in the camp of limiting the scope of his testimony, instead of grappling with his qualifications or his intended testimony's reliable basis. Once again, those questions can be dealt with at trial, and the Court will not delve into them now. Defendants' motion to exclude Dr. Kohli's testimony is therefore denied.[11]

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[10] That being said, an expert cannot tell the jury what conclusion he thinks it should reach. *Hygh v. Jacobs*, 961 F.2d 359, 363 (2d Cir. 1992). Dr. Kohli must keep his opinions carefully circumscribed so as to avoid the extra step of indicating to the jury that it should find defendants liable as a consequence.

[11] Once again, defendants also move to exclude Dr. Kohli's opinions as to alternative safer procedures, and once again that issue will be dealt with on summary judgment.

4. Jimmy Mays, Ph.D.

Coloplast moves to exclude Dr. Mays's report on two general bases and one specific. Generally, defendants claim that Dr. Mays's opinions are neither reliable nor relevant, and partially argue that he is not qualified to give them. Specifically, defendants once again try to pare down Dr. Mays's opinions by limiting the scope of what he is qualified to testify about as an expert.[12] As with plaintiffs' other experts, the Court reserves any narrow decisions about the range of Dr. Mays's testimony until trial.

But Coloplast's motion concerning the general reliability and relevance of Dr. Mays's opinions is nevertheless ripe. Defendants make five arguments along those lines. First, defendants claim that Dr. Mays's opinions are unreliable because he has failed to adequately grapple with scientific literature undermining the notion that polypropylene breaks down after it is implanted in a patient. Remember, Dr. Mays's area of expertise is the capacity of polypropylene to break down and cause injury, so a failure to grapple with alternative causes would certainly do damage to Dr. Mays's report.

[12] Defendants do not generally challenge Dr. Mays's credentials, but for the sake of completeness, Dr. Mays received a Ph.D. in Polymer Science in 1984. Mays Report 2. He then worked as a research chemist until 1988, when he became a chemistry professor. *Id.* at 2-3. He has taught that subject ever since. *Id.* at 3.

Unfortunately for Coloplast, Dr. Mays *does* consider and reject in his report the exact literature defendants point to. Dkt. 58-3 ("Mays Report"), p. 26 (discussing "Thames et al." report attributing supposed degradation of polypropylene to failure to properly clean extracted polypropylene but nevertheless rejecting opinion of Thames report as improbable based on other research). Defendants' first argument is meritless and must be rejected.

Second, Coloplast argues that Dr. Mays's opinions are unreliable because he erroneously assumes that the human body continuously releases oxidants as part of a foreign body response to polypropylene. Defendant also objects to Dr. Mays taking the further step to claim that those oxidants will eventually overcome Altis's antioxidant safety mechanisms. Shorn of oxidant protections, Dr. Mays posits that the mesh will break down.

However, once again the Baccaros correctly point to scientific support in Dr. Mays's opinion for his contentions that consistent emissions of oxidants will break an Altis down. Mays Report 28 (providing citations for principle that "[a]nti-oxidants are preferentially consumed by the oxidizing species and over a period of months their concentration falls below a level required to protect the polymer and oxidative degradation occurs"). Pairing Dr. Mays's nearly forty years of experience in polymer chemistry with citations to scientific literature supporting his claim makes for a reliable methodology.

Id. at 2-3 (establishing Dr. Mays's experience working in polymer chemistry since 1983).

In short, Dr. Mays's opinions are not the naked assumptions defendant claims them to be, and those opinions will not be excluded. *See, e.g.*, *Linde v. Arab Bank, PLC*, 922 F. Supp. 2d 316, 322 (E.D.N.Y. 2013) (finding expert's methodology reliable because it was built on expert's "professional experience and independent research").

Third, Coloplast argues that even assuming that Dr. Mays's opinion that other polypropylene meshes will break down over time is reliable, he has failed to provide any evidence that Altis will suffer the same fate. In making that argument, defendants make much of the fact that Dr. Mays admits that he has never tested Altis to see if it would survive better than the other meshes he has tested.

But none of those arguments serves to make Dr. Mays's opinion unreliable. Dr. Mays's experience with polypropylene fibers and his research into how the human body responds to them—and vice versa—provides a reliable basis for him to opine that Altis would respond similarly. *See Linde*, 922 F. Supp. 2d at 322. Defendants are free to address his lack of experimentation with Altis specifically on cross-examination to attack his credibility. However, Dr. Mays's supported opinion that Altis will break down after implantation despite defendants' preventative measures is

reliable and admissible. *See, e.g.*, *In re Ethicon, Inc.*, 2016 WL 4958282, at *3 (S.D. W. Va. Aug. 25, 2016) (upholding Dr. Mays's opinions about polypropylene breaking down in human body despite defendants' objection that he failed to test their unique mesh).

For their fourth argument to exclude Dr. Mays, defendants turn their attention to Dr. Mays's qualifications. More precisely, defendants assert that Dr. Mays is not qualified to testify that Altis would stiffen as it broke down in the body. In the same vein, defendants argue that Dr. Mays is not qualified to testify concerning whether Kelli's Altis broke down at all.

As to the more general principle of Dr. Mays's testimony concerning the mechanical effects of oxidation on polypropylene polymers, Coloplast's argument is unavailing. Once again, Dr. Mays is well into his fourth decade of experience as a polymer chemist, and his report specifically cites to several sources supporting the notion that "polypropylene becomes stiffer and embrittled" as it oxidizes. Mays Report 14. That methodology is as reliable now as it was before. *See Linde*, 922 F. Supp. 2d at 322. Even so, defendants once again are welcome to point out Dr. Mays's lack of hands-on experience with Altis on cross-examination.

The fifth and final issue Coloplast brings to the table grapples with whether Dr. Mays's report has any purpose in the absence of any indication

that Kelli's Altis actually broke down. That argument presents a mixed attack on Dr. Mays's qualifications and the relevance of his testimony.

First, defendants argue that Dr. Mays is not qualified to offer an opinion as to whether Kelli's Altis actually broke down. In one sense, defendants are correct, but in another defendants' argument is beside the point. The task of testifying as to what caused Kelli's symptoms is Dr. Gold's to carry out, so although it may be true that Dr. Mays cannot establish that Altis's degradation would have caused Kelli's symptoms, it is not necessary to the Baccaros' case for him to do so.

However, according to Coloplast, the answer to the question of his qualifications raises another one: if Dr. Mays cannot testify that Kelli's Altis would have deteriorated causing her distress, what relevance does his testimony have in the first place? But again, defendants seem to be missing the point. The Baccaros have supplied several experts, each designed to serve a particular purpose. If Dr. Mays testifies that an Altis begins to become more rigid due to the human body's foreign body response shortly after implantation, making it more rigid, that testimony would be relevant because it would work in concert with plaintiffs' other experts.

Dr. Mays's testimony that Altis breaks down and becomes stiffer informs Drs. Rosenzweig and Kohli's testimony that the relative stiffness of Altis poses dangers from the outset. Dr. Gold then ties those pieces of testimony

into the greater whole and explains that these flaws caused Kelli's symptoms. Accordingly, Dr. Mays's testimony remains relevant and is admissible. *See, e.g.*, *Nunez v. Coloplast Corp.*, 2020 WL 2315077, at *3-4 (S.D. Fla. May 11, 2020) (upholding Dr. Mays's testimony despite challenges that defendant's mesh was "unique," that Dr. Mays relied on unfounded assumptions of breakdowns in mesh's mechanical properties and foreign response in humans). Defendants' motion to exclude must therefore be denied.

5. Peggy Pence, Ph.D.

The final expert that Coloplast looks to undermine is Dr. Pence. Dr. Pence is a microbiologist, toxicologist, and pharmacologist whose presented area of expertise is the development of medical devices. Dkt. 60-8 ("Pence Report"), p. 9. Nevertheless, defendants attempt to poke holes in Dr. Pence's qualifications, as well as the reliability and relevance of her opinions.

First, Coloplast argues that Dr. Pence is not qualified to testify concerning defendants' testing, their informational documents, or their post-marketing surveillance. As the Baccaros correctly counter, though, several courts have held to the contrary. *See, e.g.*, *Sanchez v. Bos. Sci. Corp.*, 2014 WL 4851989, at *33 (S.D. W. Va. Sept. 29, 2014) (finding Dr. Pence qualified to testify concerning branding, testing, and development of vaginal mesh products). This Court agrees, and finds Dr. Pence qualified to testify concerning the

adequacy of defendants' testing processes, surveillance, and product instructions. Dr. Pence has spent forty-five years developing and marketing medical devices. Pence Report 9. Combined with her training in microbiology, toxicology, and pharmacology, the Court is satisfied that notwithstanding Dr. Pence's lack of a medical degree, she is qualified to testify as to how to market a medical device. *Id.*

As for reliability, Coloplast takes issue with three dimensions of Dr. Pence's report. First, Defendants argue that her report should be excluded because she has not provided a reliable basis for her opinions concerning the adequacy of defendants' testing. In particular, defendants decry Dr. Pence's failure to point to any regulatory standard that commands defendants to perform tests that they did not. The Baccaros agree that she does not rely on a binding standard. Instead, plaintiffs argue that Dr. Pence appropriately synthesized guidelines suggested by nonbinding sources to support her opinion as to the adequacy of defendants' testing.

Coloplast's argument again seems to be chafing against the notion of the Baccaros using expert opinions at all more than attacking those opinions on their merits. If defendants violated clear FDA standards, why would plaintiffs need to call Dr. Pence in the first place? Once again, litigators retain experts for the exact purpose of explaining grey areas in complicated fact patterns. *See* FED. R. EVID. 702(a) (noting that expert opinions must be

helpful to factfinder). In that light, the Court takes no issue with Dr. Pence testifying that based on her extensive experience in medical device marketing defendants should have done more, even if they weren't legally required to do so. Other courts have reached the same conclusion. *See Sanchez*, 2014 WL 4851989, at *33-34 (noting that Dr. Pence's reliance on non-binding sources did not render her opinions unreliable).

Second, Coloplast takes issue with the reliability of Dr. Pence's testimony concerning the adequacy of Altis's use instructions. However, that testimony would only be relevant to the extent that the instructions failed to adequately warn physicians concerning Altis's risks. As discussed below, the Baccaros' failure to warn claims cannot survive summary judgment. Regardless of the reliability of Dr. Pence's opinions in this area, her testimony would no longer be relevant. Accordingly, that testimony must be excluded. *See In re Ethicon, Inc., Pelvic Repair Sys. Prods. Liab. Litig.*, 2014 WL 186872, at *20 (S.D. W. Va. Jan. 15, 2014) (excluding opinion of inadequacy of use instructions because failure to warn claim did not survive summary judgment).

Third, Coloplast argues that Dr. Pence's opinions about defendants' post-marketing surveillance are also unreliable. In so doing, defendants return to the well in arguing that Dr. Pence inappropriately relies on non-binding authorities. Just as was the case above, the Court disagrees.

Dr. Pence is entitled to synthesize disparate pieces of literature concerning appropriate post-marketing surveillance into an opinion as to whether defendants did enough to make sure that Altis is a sufficiently safe product.[13] *See, e.g.*, *Sanchez*, 2014 WL 4851989, at *33-34 (noting that opinions based on non-binding recommendations for appropriate marketing practices are admissible).

The Court has reviewed the remainder of Coloplast's objections to Dr. Pence's testimony. One and all, these are better addressed at trial. Accordingly, Dr. Pence's intended testimony is admitted except concerning the adequacy of defendants' use instructions. The Court also reserves judgment to limit the scope of what Dr. Pence may testify about if and when she takes the stand.

[13] In the alternative, defendants argue that Dr. Pence's opinion concerning post-market testing should be excluded automatically because she relies on a database containing reports of adverse effects that other courts have refused to consider. That argument reads those cases much too broadly. Essentially, some plaintiffs in pelvic mesh cases have attempted to use Dr. Pence to include evidence that the defendant failed to report an adverse consequence to the FDA. *See, e.g.*, *Winebarger v. Bos. Sci. Corp.*, 2015 WL 1887222, at *22 (S.D. W. Va. Apr. 24, 2015). Courts have justifiably found this evidence to be irrelevant to those plaintiffs' state law claims and excluded testimony that relied "exclusively" on this database. *Id.* Defendants' citations are inapposite. In this case, Dr. Pence has provided other sources to support her opinion that defendants should have done more post-market testing. Additionally, plaintiffs have already disavowed any intention to have Dr. Pence testify concerning any failure on defendants' part to report adverse consequences. Defendants' alternative argument is thus moot.

B. Summary Judgment

Having sorted out which experts—and to a much lesser extent which opinions—will be admissible at trial, the Court will now consider Coloplast's motion for summary judgment.

1. Specific Causation

Coloplast begins its arguments on the merits by claiming that the Baccaros have failed to establish specific causation for any of their claims. To defendants' point, plaintiffs usually need expert support for both general and specific causation in a products liability case. *Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 268 (2d Cir. 2002). General causation determines whether a product is capable of causing an injury to a member of the public who encounters it, while specific causation determines whether the product in fact caused the plaintiff's claimed damages. *In re Mirena*, 387 F. Supp. 3d at 337.

Coloplast argues that the Baccaros have failed to prove specific causation because their only expert designated to testify as to that element is Dr. Gold. Because defendants argue that Dr. Gold's testimony must be precluded, plaintiffs' complaint fails with him. It would seem that the Court already gave the outcome of this argument away; as discussed above, Dr. Gold's testimony is reliable and relevant, and he is qualified to give it. Defendants'

motion for summary judgment must be denied to the extent it relies on plaintiffs' supposed failure to establish a jury question on specific causation.

2. Manufacturing Defect

However, Coloplast also raised objections to each of the Baccaros' claims on an individual basis. To that end, the Court will first consider the viability of plaintiffs' product liability claims, starting with their claim of a manufacturing defect.

A manufacturing defect involves "some mishap in the manufacturing process itself, improper workmanship, or . . . defective materials [being] used in [the] construction" of the product. *Colon ex rel. Molina v. BIC USA, Inc.*, 199 F. Supp. 2d 53, 85 (S.D.N.Y. 2001) (citing *Caprara v. Chrysler Corp.*, 417 N.E.2d 545, 552-53 (N.Y. 1981) (Jasen, J., dissenting)). A plaintiff's case thus turns on her ability to show that "the unit in question deviates in quality and other performance standards from all other identical units." *Fogel ex rel. A.F. v. Sorin Grp. USA, Inc.*, 346 F. Supp. 3d 534, 542 (S.D.N.Y. 2018). As a consequence, if the plaintiff fails to point to some defect unique to the product she purchased as compared to the product on the market generally, her claim fails on the whole. *Bertini v. Smith & Nephew, Inc.*, 8 F. Supp. 3d 246, 257 (E.D.N.Y. 2014).

Coloplast takes the position that the Baccaros have failed to point to any defect in the manufacturing process of Kelli's Altis that has caused her

injury. Plaintiffs respond with a general citation to Dr. Rosenzweig's report claiming that her Altis was "made of stiff and heavy old construction plastic" defendants' manufacturing process caused to degrade. Yet the Court has found no mention in Dr. Rosenzweig's report of any failures or flaws unique to Kelli's Altis implant owed to faulty manufacturing. The record is similarly silent as to any other evidence that Kelli's plastic was uniquely damaged or uncharacteristically poor, instead of simply being plastic of the sort Altis is usually made from. In the absence of any evidence to support an essential element of a manufacturing defect claim, those claims must be dismissed.[14]

3. Failure to Warn

A plaintiff bringing a claim of failure to warn under New York law "must demonstrate that the warning [the manufacturer provided] was inadequate and that the failure to adequately warn of the dangers was a proximate cause of his or her injuries." *Figueroa*, 254 F. Supp. 2d at 369-70 (cleaned up). In prescription medical device cases like this one, though, the customer is not the decisionmaker in selecting a product—the physician is. To ensure that the manufacturer cannot simply pass its burden to warn on to the physician, courts have crafted the "learned intermediary" doctrine to ensure that a

[14] To the extent that plaintiffs claim both strict liability and negligence to support their manufacturing defect claims, both share the same flaw and must be dismissed. *Colon*, 199 F. Supp. 2d at 85 (noting that plaintiff must prove manufacturing mishap under either strict liability or negligence theories of manufacturing defect claim).

plaintiff can still prove proximate cause notwithstanding a doctor's ultimate responsibility in making the choice of prescription. *See id.*

Functionally, the learned intermediary doctrine expands the manufacturer's duty to warn "of all potential dangers [of] which it knows or should know" to the medical profession as a whole. *See Figueroa*, 254 F. Supp. 2d at 370. If the manufacturer appropriately warns the plaintiff's treating physician, then, it has carried out its duty and cannot be held liable for a failure to warn. *Id.*

Coloplast argues that the Baccaros have failed to provide evidence to allow a reasonable jury to conclude that defendants failed to adequately warn Dr. Marici about the risks Altis poses. Plaintiffs counter by arguing that Altis's warnings and use instructions fail to mention its heightened risks of negative outcomes through its relatively small pores, stiff materials, and overall density.

But the Baccaros' arguments would bend the learned intermediary doctrine out of shape by giving the physician's responsibility to the manufacturer. Coloplast was only obliged to flag potential side effects for Dr. Marici, and once defendants did so it was up to him to weigh the risks of Altis as compared to other SUI treatment options and decide how best to treat Kelli. *Alston v. Caraco Pharm., Inc.*, 670 F. Supp. 2d 279, 284

(S.D.N.Y. 2009) (holding that responsibility to "balance the risks against the benefits of various . . . treatments" is the physician's, not the manufacturer's).

In fact, New York courts routinely reject failure to warn claims if the manufacturer provided a physician a warning concerning every side effect the plaintiff experiences. *See Alston*, 670 F. Supp. 2d at 284 (collecting cases to support that "[i]t has long been the law in New York that prescription medicine warnings are adequate when, as here, information regarding 'the precise malady incurred' was communicated in the prescribing information"). Dr. Marici testified at his deposition that the warnings he received from Altis covered every symptom afflicting Kelli. Dkt. 48-8, p. 12. Accordingly, Dr. Marici was warned about the "precise malad[ies]" that Kelli experienced, and the obligation to weigh the risks of those maladies coming about fell to him, not to defendants. *See, e.g.*, *Alston*, 670 F. Supp. 2d at 284. The Baccaros' failure to warn claims must be dismissed.[15]

4. <u>Design Defect</u>

A plaintiff must prove three elements to establish a claim for a design defect: "(1) the product as designed posed a substantial likelihood of harm; (2) it was feasible to design the product in a safer manner; and (3) the

[15] Once again, plaintiffs' failure to prove a strict liability failure to warn claim is equally fatal for their negligence claim to the extent it relies on defendants' failure to warn. *Martin v. Hacker*, 628 N.E.2d 1308, 1311 n.1.

defective design was a substantial factor in causing [the plaintiff's] injury."[16] *Argonaut Ins. Co. v. Samsung Heavy Indus. Co.*, 929 F. Supp. 2d 159, 171-72 (N.D.N.Y. 2013).

The ultimate inquiry for a design defect claim is whether, "if the design defect were known at the time of manufacture, a reasonable person would conclude that the utility of the product did not outweigh the risk inherent" in marketing it. *Warnke v. Warner-Lambert Co.*, 799 N.Y.S.2d 666, 669 (Sup. Ct. App. Div. 3d Dep't 2005) (*Voss v. Black& Decker Mfg. Co.*, 450 N.E.2d 204, 208 (N.Y. 1983)). The cost/benefit analysis for a design of a product often involves looking at several factors, including:

> (1) the utility of the product to the public as a whole and to the individual user; (2) the nature of the product—that is, the [intrinsic] likelihood that it will cause injury; (3) the availability of a safer design; (4) the potential for designing and manufacturing the product so that it is safer but remains functional and reasonably priced; (5) the ability of the plaintiff to have avoided injury by careful use of the product; (6) the degree of awareness of the potential danger of the product which reasonably can be attributed to the plaintiff; and (7) the manufacturer's ability to spread any cost related to improving the safety of the design.

Voss, 450 N.E.2d at 208-09.

[16] There is little difference between strict liability and negligence claims sounding in design defect under New York law. *Colon*, 199 F. Supp. 2d at 83 ("[F]or the purposes of analyzing a design defect claim, the theories of strict liability and negligence are virtually identical.").

Part and parcel of the plaintiff's proof that a product's value is not worth its dangers is proving that the product could have been designed more safely. *See Maxwell v. Howmedica Osteonics Corp.*, 713 F. Supp. 2d 84, 91 (N.D.N.Y. 2010). Doing so means the plaintiff must present an alternate design that would have both: "(1) led to improved safety; and (2) been economically and technically feasible." *Id.* Clearing that hurdle usually requires an expert's opinion. *Argonaut*, 929 F. Supp. 2d at 172.

Coloplast takes issue with two dimensions of the Baccaros' showing on their design defect claims: (1) New York law does not recognize design defect claims against prescription medical device manufacturers; and (2) plaintiffs have failed to provide evidence of a feasible alternative design.

a. Viability of Design Defect Claims for Medical Devices

Coloplast argues that New York does not allow design defect claims at all against prescription-only medical devices because they are unavoidably unsafe products. In fact, according to defendants the Second Circuit has confirmed as much. *See Bravman v. Baxter Healthcare Corp.*, 984 F.2d 71, 76 (2d Cir. 1993).

Setting to one side for now the legitimacy of defendants' arguments, under New York law, a product is "unavoidably unsafe" if "in the present state of human knowledge, [it is] quite incapable of being made safe for [its] intended ordinary use." *Bravman*, 984 F.2d at 75 (citing Restatement (Second) of

Torts § 402A cmt. k (Am. Law Inst. 1975)). New York courts decline to attach strict liability for an unavoidably unsafe product's design as long as the manufacturer provides adequate directions and warnings for the product's use.[17] *Martin v. Hacker*, 628 N.E.2d 1308, 1311 (N.Y. 1993).

Understandably, design defect claims against medical technologies often run into the unavoidably unsafe product defense. And if the product at issue is a prescription medication, New York courts have helpfully ruled that the defense always applies. *Martin*, 628 N.E.2d at 1311. Unfortunately, the related question of whether the defense always applies to medical *devices* is a much more contentious topic. *See, e.g.*, *Williamson v. Stryker Corp.*, 2013 WL 3833081, at *7 (S.D.N.Y. July 23, 2013) ("[T]his Court is aware of no New York case extending the 'unavoidably unsafe' products exception to all medical devices.").

Yet Coloplast disagrees. According to defendants, the Second Circuit in *Bravman* settled the uncertainty by stretching the unavoidably unsafe product doctrine to reach all medical devices. *But see* 984 F.2d at 76 (noting that particular heart valve can be treated as unavoidably unsafe). But a careful review of that opinion makes plain that the Circuit did nothing of the sort. The *Bravman* court only said that it "believe[d] that despite the

[17] The key phrase being "strict liability." Comment k to § 402A of the Restatement (Second) of Torts provides a defense only to strict liability claims for a design defect. *See* § 402A cmt. k.

[product's] noise potential, it *may* be treated, at least at the time of [plaintiff's] surgery, as an unavoidably unsafe product." *Id.* (emphasis added). In other words, the Second Circuit has held that *a* particular mechanical heart valve may be unavoidably unsafe, not that the doctrine applies as a matter of course to all medical devices. *See id.* In any case, the precedential value of *Bravman*'s holding is less than perfectly clear, because the Circuit went on to uphold the district court's dismissal of the plaintiff's products liability claims on an alternative basis. *Id.*

As a result, the Court finds itself in limbo. After all, there is no clear test to determine whether the unavoidably unsafe defense should apply in a particular case. *See Williamson*, 2013 WL 3833081, at *7. Thus unmoored from any guiding or limiting principles, several courts in this Circuit have tended not to apply the defense to medical devices as opposed to medications. *See, e.g.*, *id.* (collecting cases); *see also Arruda*, 2020 WL 4569436, at *6 (noting in dicta that vaginal mesh was not unavoidably dangerous product).

To be fair, though, those cases often had a fallback position to protect their rulings on the application of the unavoidably unsafe product defense. For example, in *Williamson*, the Southern District only considered the unavoidably unsafe product defense on a motion to dismiss and was not obliged to make a hard ruling on whether the defense would apply later on. 2013 WL 3833081, at *7-8. Similarly, in *Arruda*, the Court was able to rely

on an exception to the unavoidably unsafe product defense—a defendant's failure to provide an adequate warning—to cushion the force of its holding that the defense did not apply. 2020 WL 4569436, at *6-7.

On summary judgment, and having already held as a matter of law that Coloplast's warnings were adequate, this Court is not nearly so insulated.[18] Unsheltered and directionless, the only guide left is the Restatement (Second) of Torts, the original source of the unavoidably unsafe product defense. Restatement (Second) of Torts, § 402A cmt. k. The Restatement clarifies that the unavoidably unsafe product doctrine is justified in medicine precisely because the consequences of disease are often so great that marketing and using a product to combat it is still almost invariably the better option regardless of the risks the product itself poses. *See id.* (referring to example of vaccine "which not uncommonly leads to very serious and damaging consequences" still being insulated from strict liability because "the disease itself invariably leads to a dreadful death").

That rationale does not carry the same force when applied to these facts. With all due concern for the embarrassing and unhygienic consequences of

[18] Worse yet, whether the unavoidably unsafe product doctrine also covers the Baccaros' negligent design claims, or if a claim of negligent design is even a distinct tort from its strict liability cousin are also open questions. *See Jarvis v. Ford Motor Co.*, 283 F.3d 33, 62-63 (2d Cir. 2002) (describing New York's unsettled caselaw concerning distinction between strict liability and negligence for design defect); *Martin*, 628 N.E.2d at 1311 (noting that unavoidably unsafe product defense is unavailable for "products negligently manufactured, negligently distributed[,] or unaccompanied by proper warnings").

SUI, the Court is not at all convinced that those consequences so convincingly outweigh the alternative of Kelli's list of symptoms as to justify a pass on strict liability. Gold Report 3 (describing Kelli's symptoms of pain, bleeding, repeated urinary tract infections, urinary incontinence, chronic pelvic inflammation, and pain during intercourse).

In that light, the Second Circuit's adoption of the unavoidably unsafe product doctrine in *Bravman* if anything cuts against applying that defense to the facts of this case. 984 F.2d at 76. There is a world of difference between a life-saving heart valve with an unexpected (but minor) side effect of excessive noise and a mesh to cure incontinence that can make the patient's problem with incontinence worse and invite a host of more debilitating consequences. *Compare id.*, *with* Gold Report 3.

What is more, another court in this district has held that the unavoidably unsafe product doctrine does not apply to a surgically-inserted vaginal mesh. *Arruda*, 2020 WL 4569436, at *4-6 (joining other courts in Second Circuit in rejecting broad application of unavoidably unsafe product doctrine to all medical devices and declining to apply it to vaginal mesh). This Court agrees. The purpose of the unavoidably unsafe product doctrine of ensuring that manufacturers are not disincentivized from producing life-saving goods due to their inherent risks is just too poor a fit for these facts. Accordingly,

defendants' reliance on the unavoidably unsafe product defense does not merit summary judgment in their favor.

b. Proof of Safer Alternative Designs

However, Coloplast is not finished with the Baccaros' design defect claims just yet. In the alternative, defendants argue that plaintiffs have failed to provide expert evidence of a feasible design. Plaintiffs respond that they have provided four through Drs. Rosenzweig and Kohli: (1) using a colposuspension procedure instead of a mesh implant; (2) using an "autologous fascia sling"; (3) using an allograft sling; and (4) using a less dense polypropylene mesh, such as a hernia mesh called UltraPro.

Yet Coloplast is still not satisfied. Instead, defendants argue that none of these procedures are safer designs, but are instead completely different products. Generally, courts have agreed with defendants that an alternative procedure or even a mesh made of a different substance does not satisfy a plaintiff's burden of proving an alternative design. *See, e.g.*, *Cosh v. Atrium Med. Corp.*, 2021 WL 1177770, at *3 (S.D.N.Y. Mar. 29, 2021) (dismissing complaint for only alleging that different product than polypropylene be used to create mesh because "alleging that the product should not be used at all is insufficient to satisfy the feasible alternative design element"); *Wood v. Am. Med. Sys. Inc.*, 2021 WL 1178547, at *5 (D. Colo. Mar. 26, 2021) (finding alternative procedures including allografts not suitable alternative designs).

For the Baccaros' first three claimed "alternative designs," Coloplast is correct. Alternative procedures or slings made of other materials are not suitable alternative designs for a polypropylene mesh and cannot satisfy plaintiffs' burden.[19] *See Wood*, 2021 WL 1178547, at *5.

UltraPro, however, is. According to Dr. Rosenzweig, UltraPro is "a sling with less polypropylene [that is] less stiff, heavy, [and] dense, [and has] larger pores," which addresses every objection he has with Altis's design. Rosenzweig Report 87. In other words, the Baccaros have submitted an expert's opinion that every design flaw Altis possesses is cured by an alternative product, which makes this alternative design safer. *See id.*; *Maxwell*, 713 F. Supp. 2d at 91 (noting that plaintiff must prove alternative design would actually be safer). Additionally, UltraPro is also available on the market, demonstrating that it is both economically and technically feasible. *See Maxwell*, 713 F. Supp. 2d at 91 (noting that plaintiff must prove alternative design would be economically and technically feasible).

Coloplast retorts that the FDA has only cleared UltraPro for use in abdominal hernias, not to treat SUI. But that argument confuses the issue. The standard cannot be that the safer design must already exist and be

[19] Obviously, then, any reference to these alternative procedures at trial would be irrelevant as a consequence.

immediately ready. Nor is it. Courts routinely treat the safer, feasible alternative design inquiry as a hypothetical. *See Urena v. ConAgra Foods, Inc.*, 2020 WL 3051558, at *9 (E.D.N.Y. June 8, 2020) (noting that expert often must establish that "hypothetical" design would be safer).

One New York trial court has disagreed and held that a lack of FDA approval precludes finding that an alternative design is feasible. *Militrano ex rel. Militrano v. Lederle Labs.*, 769 N.Y.S.2d 839, 852 (Sup. Ct. Kings Cty. 2003). Yet as far as the Court can tell, that opinion stands alone. In the absence of any indication that New York's Court of Appeals would side with that lone lower court, this Court is free to disagree with that holding. *Phila. Indem. Ins. Co. v. Indian Harbor Ins. Co.*, 434 F. Supp. 3d 4, 10 (E.D.N.Y. 2020) (noting that federal courts are not bound by decisions of a state's intermediate and lower courts because obligation of federal court is to ascertain opinion of state's highest court).

And disagree it does. Think for a second about how requiring FDA approval of an alternative design would change the design defect inquiry. No longer would a medical plaintiff need to present evidence of a hypothetical alternative product that would improve on the manufacturer's. Instead, the question would have to be whether the physician selected the proper, approved drug or device among those available. A claim of that sort would look much more like medical malpractice than defective design. *Cf. Spensieri*

v. Lasky, 723 N.E.2d 544, 545 (N.Y. 1999) (describing medical malpractice claim for physicians prescribing risky medication).

Accordingly, the Court is satisfied that the appropriate standard under New York law is the feasibility of a hypothetical alternative design, not whether an alternative design has been actively approved by the FDA for a manufacturer to use for a specific purpose. *See Maxwell*, 713 F. Supp. 2d at 91 (noting that under New York law plaintiff must prove that alternative design is safer and economically and technically feasible).

Through that lens, several courts applying the laws of other states have upheld UltraPro as a hypothetical feasible alternative to allegedly defective vaginal mesh products. *See, e.g.*, *Moultrie v. Coloplast Corp.*, 2020 WL 1249354, at *11 (W.D. Pa. Mar. 16, 2020) (upholding Dr. Rosenzweig's endorsement of UltraPro as alternative for Coloplast product under Pennsylvania law); *Schrecengost v. Coloplast Corp.*, 425 F. Supp. 3d 448, 460-61 (W.D. Pa. 2019) (same). This Court joins them, and as a consequence Coloplast's objection that the Baccaros have failed to present a feasible, safer alternative must be rejected. Defendants' arguments in favor of dismissing plaintiffs' design defect claims have both failed, and defendants' motion for summary judgment must be denied on that claim.

5. Fraudulent Concealment

Having resolved Coloplast's summary judgment motion as to the Baccaros' product liability claims, plaintiffs' next batch of torts stems from defendants' alleged deceptions in marketing Altis. The analysis for plaintiffs' fraudulent concealment and negligent misrepresentation claims is strikingly similar, but nevertheless distinct.

As for fraudulent concealment, a plaintiff looking to prove that claim under New York law must establish six elements: "(1) a duty to disclose material facts; (2) knowledge of material facts by a party bound to make such disclosures; (3) failure to discharge a duty to disclose; (4) scienter; (5) reliance; and (6) damages." *De Sole v. Knoedler Gallery, LLC*, 137 F. Supp. 3d 387, 410 (S.D.N.Y. 2015).

A plaintiff can satisfy her burden of proving a duty to disclose through two methods. First, the plaintiff can go the traditional route of establishing a "confidential, fiduciary or other 'special' relationship" between the parties. *Canpartners Invs. IV, LLC v. Alliance Gaming Corp.*, 981 F. Supp. 820, 826 (S.D.N.Y. 1997). Second, the plaintiff can establish that the defendant possessed superior knowledge which was not readily available to the plaintiff; and the defendant knew that the plaintiff was acting on the basis of mistaken knowledge. *Id.*

Unfortunately for the Baccaros, Dr. Marici's testimony that he did not rely solely on any manufacturer warnings in choosing Altis puts a significant damper on their ability to prove reliance. Dkt. 48-8, pp. 10-11. Plaintiffs need to prove some causal connection between Coloplast's allegedly concealing information that should have been in the instructions for use and Kelli's injury. But unlike the usual case, plaintiffs did not select Altis, Dr. Marici did. So to properly tie Kelli's injury to any concealment on defendants' part, plaintiffs must prove that Dr. Marici would not have chosen Altis if defendants had properly disclosed its risks. However, Dr. Marici testified that he chose Altis not based on any representations in defendants' use instructions, but because of his own experience and his conversations with colleagues. *Id.*

Even assuming for the moment that Coloplast's superior knowledge was enough to bypass Dr. Marici's presence as an intermediary, this testimony makes proving reliance a task too tall for the Baccaros to conquer. No reasonable juror could conclude that Dr. Marici relied on defendants to draw his attention to the possibility that Altis's particular design features may elevate the risks of the side effects it already warned about. The only evidence on the record about Dr. Marici's decision-making process in choosing Altis was that he was aware of every side effect Kelli experienced, but he

nevertheless chose Altis because he believed it was the correct product based on his experience and his conversations with colleagues. Dkt. 48-8, pp. 10-11.

In the absence of any arguments from plaintiffs to explain how their evidentiary showing would support their claim of fraudulent concealment, that claim must be dismissed.

6. Negligent Misrepresentation

A plaintiff hoping to establish negligent misrepresentation under New York law must prove each of five elements: (1) a special relationship between the plaintiff and defendant that imposes a duty to give correct information; (2) a false representation by the defendant that it should have known was correct; (3) the defendant knew the plaintiff wanted that information for a serious purpose; (4) reasonable reliance by the plaintiff; and (5) injury caused by that reliance. *See Hydro Inv., Inc. v. Trafalgar Power Inc.*, 227 F.3d 8, 20 (2d Cir. 2000).

As implied by the "special relationship" element, "not all representations made by a seller of goods will give rise to a duty to speak with care." *Dallas Aerospace, Inc. v. CIS Air Corp.*, 352 F.3d 775, 788 (2d Cir. 2003) (citing *Kimmell v. Schaefer*, 675 N.E.2d 450, 454 (N.Y. 1996)) (cleaned up). Instead, a special relationship contemplates a closer degree of trust. *Dallas Aerospace*, 352 F.3d at 788. That relationship must be "privity-like,"

fiduciary, or one in which a party either has "unique or specialized expertise" or is "in a special position of confidence and trust with the injured party." *Mandarin Tr. Ltd. v. Wildenstein*, 944 N.E.2d 1104, 1109 (N.Y. 2011).

The Baccaros would be hard-pressed to prove a special, "privity-like" relationship between themselves and Coloplast when Dr. Marici was interposed between the two parties. Similarly, plaintiffs have failed to raise any arguments to justify keeping their negligent misrepresentation claim alive. Accordingly, that claim must also be dismissed. *See, e.g.*, *Bruno v. Zimmer, Inc.*, 2017 WL 8793242, at *10 (E.D.N.Y. Aug. 11, 2017) (dismissing claim of negligent misrepresentation for same reasons as fraudulent concealment).

7. Gross Negligence

At this point, the Court has determined that there is a viable jury question only for the Baccaros' design defect claims. In case any of plaintiffs' substantive claims survived, defendants framed their motion for summary judgment to not only argue that defendants did not engage in any actionable wrongdoing but also that any wrongdoing they might have engaged in was relatively muted.

In other words, Coloplast argues that there is no evidence to support a claim of gross—rather than garden variety—negligence. Under New York law, gross negligence is "conduct that evinces a reckless disregard for the

rights of others or 'smacks' of intentional wrongdoing." *Am. Tel. & Tel. Co. v. City of N.Y.*, 83 F.3d 549, 556 (2d Cir. 1996). In other words, "the act or omission must be of an aggravated character, as distinguished from the failure to exercise ordinary care." *Curley v. AMR Corp.*, 153 F.3d 5, 13 (2d Cir. 1998). In short, to prove gross negligence, a plaintiff must prove by a preponderance of the evidence that the defendant "not only acted carelessly in making a mistake, but was so extremely careless that it was equivalent to recklessness." *Travelers Indem. Co. v. Losco Grp., Inc.*, 204 F. Supp. 2d 639, 644 (S.D.N.Y. 2002).

Coloplast argues that the Baccaros have failed to point to any evidence of reckless conduct that would enable them to establish gross negligence. Plaintiffs respond by relying on Dr. Rosenzweig's report, which notes that defendants had access to data supporting the dangers of smaller pore sizes in vaginal mesh as early as 2007. Rosenzweig Report 35. As defendants helpfully point out in their reply, that information came to light five years before Altis got the FDA's blessing.

But if anything, that argument cuts against Coloplast. That defendants were allegedly aware for much of Altis's development cycle that an intentional design choice on their part posed risks over and above alternative options shifts the calculus far enough to make the question of defendants' recklessness fit for a jury.

As alternative defenses, Coloplast argues that Dr. Rosenzweig's opinions as to defendants' awareness of the alleged dangers of small pores should be excluded and that the FDA has cleared them to sell Altis. On the first point, to the extent that defendants argue that this particular opinion of Dr. Rosenzweig's is unreliable and should be excluded that argument must be rejected. Defendants did not raise that argument at any point in their *Daubert* motion, and the Court will not consider it for the first time on a reply brief to a motion for summary judgment. *See Graham v. Henderson*, 89 F.3d 75, 82 (2d Cir. 1996) (declining to consider argument raised for first time in reply brief).

Coloplast's final argument that the FDA's benediction somehow shields defendants from a charge of gross negligence must also be rejected. Setting a medical device manufacturer's responsibility to take care that their products are safe only at the bare minimum for FDA approval would create perverse incentives that this Court will not abide. A defendant who is aware that its product creates an outsized risk of harm but does nothing to reduce that risk acts recklessly regardless of whether the FDA has sanctioned the product's current design.[20]

[20] FDA approval may provide evidence that a manufacturer acted reasonably, but not enough to merit summary judgment against a gross negligence claim.

The Baccaros have provided evidence that Coloplast did precisely that. According to Dr. Rosenzweig, defendants knew from the jump that small pores increased the likelihood of complications, and designed Altis with relatively small pores anyway. Rosenzweig Report 35. A reasonable jury could conclude that defendants were grossly negligent in sticking with the small pore design for the Altis. Plaintiffs' claim for gross negligence must survive.

8. Punitive Damages

Alternatively, Coloplast argues that the Baccaros have failed to establish that they are entitled to punitive damages. "Under New York law, the decision to award punitive damages and their amount are questions which primarily reside in the jury's discretion." *Racich v. Celotex Corp.*, 887 F.2d 393, 397 (2d Cir. 1989). Typically, then, courts do not grant summary judgment "where there is enough evidence to permit the jury to find that defendants acted with wanton and reckless or malicious intent." *Morales v. Kavulich & Assocs., P.C.*, 294 F. Supp. 3d 193, 199 (S.D.N.Y. 2018).

For the same reasons that the Baccaros' showing supports a claim of gross negligence, plaintiffs have presented a jury question as to whether Coloplast "acted with wanton and reckless or malicious intent." *Morales*, 294 F. Supp. 3d at 199. In marketing Altis when there was evidence that its

design posed a greater risk than alternatives, a reasonable jury could conclude that defendants acted recklessly. The Court will not take that question from the jury, and defendants' motion for summary judgment on plaintiffs' claim for punitive damages must be denied.

9. Loss of Consortium

Finally, Coloplast argues for summary judgment against Brian's loss of consortium claim. Brian's claim relies on defendants' alleged misconduct denying him Kelli's services, society, consortium and companionship. From their perspective, this claim is derivative of Kelli's claims, and must be dismissed for the same reasons.

But the Baccaros' design defect claims survived defendants' motion for summary judgment. Accordingly, Brian's loss of consortium claim is still viable. Defendants' motion for summary judgment against this claim must be denied. *See, e.g.*, *Grill v. Philip Morris USA, Inc.*, 653 F. Supp. 2d 481, 497-98 (S.D.N.Y. 2009) (denying motion for summary judgment on derivative loss of consortium claim when summary judgment was denied as to one or more underlying claims).

V. CONCLUSION

Often in fact patterns as medically involved as this one, most of the difficulty comes down to ensuring that the plaintiff has enough expert testimony to help the jury navigate her claims. To a certain extent, that

proved to be the case here. In addition, though, much of the Baccaros' claims involved hypotheticals, abstract causation questions, and complex issues of biological engineering that posed their own unique walls to recovery. But the smoke has cleared, and after sorting through defendants' motions, only one of plaintiffs' substantive claims remains. That claim must be brought to trial.

Therefore, it is

ORDERED that

1. Defendants' motion to exclude the testimony of William Gold, M.D. is GRANTED in part and DENIED in part;
2. Dr. William Gold's testimony concerning polypropylene's capacity to break down in the human body is excluded;
3. Defendants' motion to exclude the testimony of Bruce Rosenzweig, M.D. is GRANTED in part and DENIED in part;
4. Dr. Bruce Rosenzweig's intended testimony concerning whether Altis's failure to include a sheath or four-pointed anchors are design defects is excluded;
5. Defendants' motion to exclude the testimony of Neeraj Kohli, M.D. is DENIED;
6. Defendants' motion to exclude the testimony of Jimmy Mays, Ph.D. is DENIED;

7. Defendants' motion to exclude the testimony of Peggy Pence, Ph.D. is GRANTED in part and DENIED in part;

8. Dr. Peggy Pence's intended testimony is excluded to the extent she intends to testify concerning the adequacy of defendants' use instructions;

9. Defendants' motion for summary judgment is GRANTED in part and DENIED in part;

10. Plaintiffs Kelli Lynn Baccaro and Brian Scott Baccaro's claims under counts: (II) negligent misrepresentation; (V) failure to warn; (VI) manufacturing defect; and (VII) fraudulent concealment are DISMISSED; and

11. Plaintiffs Kelli Lynn Baccaro and Brian Scott Baccaro's claims under counts: (I) negligence; (III) gross negligence; (IV) design defect; (VIII) Punitive damages; and (IX) loss of consortium remain for trial.

IT IS SO ORDERED.

Dated: July 22, 2021
Utica, New York.

David N. Hurd
U.S. District Judge